IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF SOUTH DAKOTA

TERRI BRUCE, *Plaintiff,* v. STATE OF SOUTH DAKOTA and LAURIE GILL, in her official capacity as Commissioner of the South Dakota Bureau of Human Resources *Defendants.*	)	Case No. 17-5080

SUPPLEMENTAL EXPERT DISCLOSURE REPORT OF GEORGE RICHARD BROWN, MD, DFAPA

I, George R. Brown, have been retained by counsel for Plaintiffs as an expert in connection with the above-captioned litigation.

1. On March 18, 2018, I signed an expert report setting forth my opinion on: (1) the medical condition known as gender dysphoria; (2) the prevailing treatment protocols for gender dysphoria; and (3) whether there is a legitimate medical basis for exclusion (ww) in the South Dakota State Employee Health Plan for Fiscal Year 2015 ("SDSEHP" or the "Plan") at page 56, which categorically excludes coverage for "[s]ervices or drugs related to gender transformations."

2. In my initial report I concluded: There is no dispute in the mainstream medical community that transition-related care, including cross-sex hormone therapy and gender confirmation surgery, treats an "illness" or "condition," and that such care "meet[s] accepted standards of medicine."

3. In my original report, I also noted that I may supplement these opinions in response to information produced by Defendants in discovery or in response to Defendants' expert disclosures. I now provide this report to supplement that expert opinion in response to Defendants' Answer to Plaintiff's First Set of Interrogatories, which is attached as Exhibit A.

4. I have knowledge of the matters stated in this report and have collected and cite to relevant literature concerning the issues that arise in this litigation.

5. I may further supplement these opinions in response to information produced by Defendants in discovery or in response to Defendants' expert disclosures.

The CMS Decision Memo

6. Defendants' response to the interrogatories mischaracterizes a recent decision by the U.S. Department of Health & Human Services Center for Medicare and Medicaid Services ("CMS"). Defendants' discussion of the CMS document appears to be drawn from an article by Peter Sprigg posted on the website of the Family Research Council. Mr. Sprigg is a Protestant minister. He is not a clinician and holds no medical credentials. Family Research Council is a religious advocacy organization whose "mission is to advance faith, family, and freedom in public policy and the culture from a Christian worldview." https://www.frc.org/mission-statement.

7. As I discussed in my original report, an impartial adjudicative board in the Department of Health & Human Services concluded in 2014, based on decades of studies, that surgical care to treat gender dysphoria is safe, effective, and not experimental. *See* Exhibit B. The decision specifically noted that, regardless of whether the studies were randomized double-blind trials, there was sufficient evidence to prove "a consensus among researchers and mainstream medical organizations that transsexual surgery is an effective, safe and medically

necessary treatment for [gender dysphoria]." *Id.* at 20. Ever since the adjudicative board's decision, Medicare has provided coverage for transition-related surgery based on patients' individual needs.

8. In the document referenced by Defendants, CMS decided to continue covering surgery based on patients' individual needs and refrain from issuing national standards regarding how do determine medical necessity in individualized cases. *See* Exhibit C. The decision specifically clarified that "GRS [gender reassignment surgery] may be a reasonable and necessary service for certain beneficiaries with gender dysphoria," but "[t]he current scientific information is not complete for CMS to make a [national coverage determination] that identifies *the precise patient population* for whom the service would be reasonable and necessary." *Id.* at 54 (emphasis added). In particular, CMS expressed concern that the Medicare population includes "older adults [who] may respond to health care treatments differently than younger adults." *Id.* at 57. "These differences can be due to, for example, multiple health conditions or co-morbidities, longer duration needed for healing, metabolic variances, and impact of reduced mobility." *Id.* Indeed, most studies on outcomes of patients with gender dysphoria include only a minority of individuals over the age of 65, which is not uncommon in medical studies that are not focused on geriatric issues.

9. The CMS memorandum concluded that the appropriateness of surgical care for this population should be determined on an individualized basis. Indeed, most medical and surgical care provided to patients should be individualized, taking into account each patient's unique clinical circumstances. By contrast, exclusion (ww) in the SDSEHP does not evaluate the medical necessity of care for gender dysphoria on an individualized basis. It categorically excludes all coverage regardless of an individualized showing of medical necessity.

10. Relying on the CMS decision, Defendants' response to the interrogatories also notes that there are no "double-blind" scientific studies regarding the efficacy of surgical care for gender dysphoria. But medical standards of care are not determined solely by double-blind studies, especially in the context of surgery. Double-blind studies with "sham" surgeries are often impossible or unethical to conduct.

11. If the SDSEHP limited all medical care to surgical procedures supported by prospective, controlled, double-blind studies, then only a very few medical conditions would ever be covered. For example, one of the most common surgical procedures performed in the United States is tonsillectomy, with over 530,000 cases completed a year, using multiple, competing surgical techniques. However, a review of the evidence base for this very common procedure, including when to apply it and the best surgical techniques to utilize, is not supported by "double blind" controlled studies in spite of the common use of this treatment over centuries (see Baugh R, Archer S, Mitchell R, et al: Clinical Practice Guideline: Tonsillectomy in Children, Otolaryngology–Head and Neck Surgery Vol 144, Issue 1,suppl, pp. S1 - S30, 2011). Baugh and coauthors noted: "While there is a body of literature from which the guidelines were drawn, significant gaps remain in knowledge about preoperative, intraoperative, and postoperative care in children who undergo tonsillectomy."

12. Similarly, acute appendicitis is one of the most common causes of acute abdominal pain in the United States. However, it remains unclear whether the common approach of appendectomy is superior to nonsurgical treatment with antibiotics in many patients. A recent Cochrane review was inconclusive: "We could not conclude whether antibiotic treatment is or is not inferior to appendectomy. Because of the low to moderate quality of the trials, appendectomy remains the standard treatment for acute appendicitis." (see Wilms IMHA, de Hoog DENM, de

Visser DC, Janzing HMJ. Appendectomy versus antibiotic treatment for acute appendicitis. Cochrane Database of Systematic Reviews 2011, Issue 11. Art. No.: CD008359. DOI: 10.1002/14651858. CD008359.pub2). In other words, the prevailing standard of care, in spite of the "low quality" of evidence in support of surgery over a nonsurgical alternative, remains the accepted standard.

13. Categorically excluding coverage for transition-related surgeries based on the lack of "double blind" prospective, controlled, double-blind studies singles out gender dysphoria and imposes an impossible standard of proof that very few surgical procedures could ever meet.

Allegation that transition-related surgery and cross-sex hormones are harmful

14. In the response to Plaintiff's First Interrogatory, Defendants assert that "[a] significant number of members in the medical field have concluded that gender transitions or transformations (including administration of hormones, cross-sex drugs, procedures, etc.) can be harmful to the patient." There are always individuals with fringe viewpoints that fall far outside the medical mainstream. But those fringe viewpoints do not define accepted standards of medicine.

15. Defendants' assertion that transition-related surgery is harmful is based on a distortion of the CMS report's discussion of scientific studies that found higher mortality rates for transgender patients when compared with the Swedish population at large. Ceclilia Dhejne, *et al.*, "Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden," PloS One, Vol. 6, p. 6 (Feb.2011). Statistically, transgender people as a group are at greater risk of experiencing those conditions as a result of the stressors inherent in being prevented from transitioning or obtaining medical care throughout all, or much, of their lives. Some studies have documented that these health disparities can persist even after

transition-related treatment because of the continuing effects of discrimination and the reality that gender dysphoria-specific treatments are not panaceas for all problems that a person may experience in their life (nor were these treatments designed to be).

16. Defendants' response to the interrogatories falsely implies that transgender people in the Dhejne study who underwent surgery had higher rates of mortality than transgender people who did not have surgery. But the Dhejne study compared transgender individuals postoperatively with the *non-transgender* population in Sweden at large. It did not compare transgender Swedes who had surgery with transgender Swedes who did not have surgery.

17. There is no support in the medical literature for Defendants' claim that transgender patients who receive surgical care for gender dysphoria in accordance with the WPATH Standards of Care have greater mortality rates than transgender patients who do not receive surgical treatment. In fact, there is some evidence that patients with gender dysphoria who would otherwise be eligible for hormones and surgery but who are unable to receive this medically necessary care are at increased risk for negative outcomes, including depression, anxiety, and suicidality.

18. Defendants' response to the interrogatories also asserts that a person's use of hormones to treat gender dysphoria creates health risks. Every medication has potential side effects, but the risks of not treating, or undertreating, a serious medical condition must also be taken into account. "Do no harm" does not equate to "Do not treat" when it comes to providing medically necessary transgender health care to those diagnosed with Gender Dysphoria. It should also be noted that cisgender males who receive the same testosterone treatments as transgender men (for hypogonadism, for example) are exposed to similar risks which clinicians must weigh

against the potential benefits. This is standard practice in all areas of medicine and not unique to transgender medicine.

19. Although Defendants suggest that transgender people may be at greater risks of developing certain cancers and thromboembolic events as a result of extended hormone use, newer literature has debunked that argument. The two largest studies published worldwide both concluded that transgender adults who receive cross-sex hormones do not have an increased risk of breast cancers when compared with transgender adults who do not receive cross-sex hormones (see Brown GR, Jones KT: Incidence of breast cancer in a cohort of 5,135 transgender veterans. Breast Cancer Research and Treatment, 149(1): pp 191-198, 2015; published online ahead of print, DOI: 10.1007/s10549-014-3213-2, 2014; Gooren LJ, van Trotsenburg MA, Giltay EJ, van Diest PJ (2013); Breast cancer development in transsexual subjects receiving cross-sex hormone treatment. J Sex Med 12:3129–3134. doi:10.1111/jsm.12319).

20. Recent studies have also demonstrated that transgender adults who receive cross-sex hormones also have no significant increased risk of major thromboembolic events once oral estrogens (particularly oral synthetic estrogens) are substituted with parenteral estrogens (e.g. estrogen patches or injectables; see Asscheman H, Giltay EJ, Megens JA, de Ronde WP, van Trotsenburg MA, Gooren LJ (2011); A long-term follow-up study of mortality in transsexuals receiving treatment with cross-sex hormones. Eur J Endocrinol 164:635–642; van Kesteren PJ, Asscheman H, Megens JA, Gooren LJ (1997) Mortality and morbidity in transsexual subjects treated with cross-sex hormones. Clin Endocrinol (Oxf) 47:337–342)).

Persistence of Gender Dysphoria After Puberty

21. Defendants' response to the interrogatories primarily addresses the issue of puberty suppressants and cross-sex hormone therapy for children. Defendants contend that

providing puberty suppressants to children is harmful because gender dysphoria does not always persist once a child reaches puberty. As support for that argument Defendants cite to an article in published in *The New Atlantis*, which is not a peer-reviewed medical journal but a quarterly publication from a socially conservative advocacy group known as the Ethics and Public Policy Center. Defendants also cite to an article by the president of the American College of Pediatricians, a small, recently founded, socially conservative group with about 500 members that should not be confused with the mainstream American Academy of Pediatrics (with over 65,000 members founded over 85 years ago), which supports transition-related care, including puberty suppressants and cross-sex hormones for transgender youth (David A. Levine & Comm. On Adolescence, Am. Acad. of Pediatrics Technical Report, Office-Based Care for Lesbian, Gay, Bisexual, Transgender, and Questioning Youth, 132 Pediatrics e297, 298 (2013)).

22. Defendants' discussion of whether gender dysphoria persists through puberty is irrelevant to this case because the Plaintiff is a transgender adult. The DMS-V diagnostic code for gender dyshporia in childhood (302.60) is different from the diagnostic code for gender dysphoria in adults (302.85) and the treatment protocols for the two diagnoses are different.

23. While some older studies have suggested that gender dysphoria in pre-pubertal youth may not always persist through puberty, there is no support in the medical literature for the notion that gender dysphoria in post-pubertal adolescents or adults will resolve itself without medical intervention. For example, in one follow-up study of adolescents treated at a gender clinic, 100% of the 70 individuals treated ultimately underwent hormone therapy and continued to identify with a gender different than the one assigned to them at birth. (de Vries, Steensma, Doreleijers, & Cohen-Kettenis, 2010). The evidence is in favor of more, not fewer, adults presenting with requests for treatment for longstanding Gender Dysphoria even late into

adulthood, largely as a result of coming to terms with this diagnosis and choosing to get treatment (see Witten T, Eyler E: Care of aging transgender and gender non-conforming patients, Chapter 18, pp 344-378, in Principles of Transgender Medicine and Surgery, Second Edition, edited by R Ettner, S Monstrey, and E Coleman, Routledge, NY, NY, 2016).

24. In my personal experience of 35 years of work, I have had no adult or late adolescent patients with gender dysphoria experience a resolution of these clinical symptoms without one or more interventions such as cross-sex hormones or surgery.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 8th day of April, 2018

George R. Brown, MD